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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,674	10/27/1999	MICHAEL NEHLS	8535-029-999	4973
20583	7590	03/22/2004	EXAMINER	
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017			MARSCHER, ARDIN H	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/428,674

Applicant(s)

NEHLS ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 12/3/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

LACK OF UTILITY

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3 and 10-14 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

This rejection is maintained and reiterated from the previous office action, mailed 6/3/03. Although the asserted utility in the instant application may be credible, the lack of the combination of a specific, substantial, and credible utility, or, in the alternative, a well-established utility still is deemed to support this rejection. Applicants argue firstly that the "claimed polynucleotides can be used as a gene probe or chromosome marker specific for such genes that are of particular interest to scientists and medical practitioners...". In response this is an allegation without factual support and therefore non-persuasive. Applicants further argue that "Just because the Applicants have not disclose[sic] what

precise biological roles do the present claimed polynucleotides have in the late stages of cellular differentiation and development does not mean that the presently described polynucleotides lack utility." ...". In response this is an allegation without factual support regarding any role in any stage late or otherwise and therefore non-persuasive. Also, in response cellular differentiation occurs in a multitude of directions for the multitude of differentiated mature cells in a human which thus also supports the lack of a specific utility due to applicants not setting forth any particular cellular differentiation direction. Applicants then argue that the claimed polynucleotides provide tools for identifying exon splice junctions, chromosome mapping, etc. ...". In response this again is an allegation without factual support and therefore non-persuasive. In particular several Genbank accession number sequence matches are set forth regarding this allegation. Several allegations of exon spanning sequence are set forth in arguments but nowhere is there an indication that such exon spanning was disclosed as filed. Applicants are reminded that utility is evaluated from the disclosure as filed and not via a later found utility. Regarding chromosome mapping, it is well known that all polynucleotide sequences have matching segments, given a variety of sequence identity criteria inclusive of even low percentages, in the large human genome. Thus, such chromosome matching utility is available generally for polynucleotides of a particular sequence and does not support a specific utility. Also, the chromosome mapping location information was not argued as being known at the time of filing of the instant application and thus was found only via further research. The need for further research to search

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for a utility also supports this lack of utility rejection. On page 6 of the REMARKS, filed 12/3/03, applicants cite page 10, lines 32-33, of the specification. Consideration of said page 10 citation reveals a series of allegations again without any factual support. Only further research may result in finding a utility in that list which applies to the instantly claimed polynucleotides. This therefore again supports this lack of utility rejection. Applicants argue further on page 7 of said REMARKS that the claimed polynucleotides provide exquisite specificity for localizing regions of disease-associated genes. In response none of such disease-associated genes localizations has been connected to any of the instantly claimed polynucleotides. Also, considering the massive size of the human genome, the claimed few polynucleotides cannot reasonably provide any such exquisiteness unless both located in a relative small genomic region and also located relatively close to at least one disease-associated gene. Neither of these conditions have been set forth for the instantly claimed polynucleotides making the exquisiteness argument non-persuasive. Applicants go on to argue that narrow definition of an asserted utility is not required. This is acknowledged, but at least some utility is required other than a claimed invention which only supplies utility via a research project of undefined complexity. This lack of narrowness argument is further set forth by applicants on page 8 of said REMARKS regarding enrichment of a class of genes via the gene trap technology. In response the class of genes has not been supported by factual support and thus is an allegation without factual basis and therefore non-persuasive. Also, the late stage stem cell differentiation argument is set forth

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again by applicant and is equally non-specific as well as non-substantial for the reasons of record as also further discussed above. Applicant then argues that utility only needs to be supported beyond a reasonable doubt. In response it is unclear what to doubt because none of the asserted utilities go beyond a research project. No disease-associated gene has been identified regarding the claimed polynucleotides, no specific mapping utility has been alleged beyond what is available for any polynucleotide generally, etc. Thus, in response this is again an allegation without factual support and therefore non-persuasive.

Applicant then argues that the instantly claimed polynucleotides cut down and thus simplify the work of a biologist for studying embryonic cell differentiation. In response this again is an allegation without factual support and therefore non-persuasive. Also, it is not seen how a positive list of polynucleotides is the same as a negative list of "cut down" or simplified work for a biologist. Applicants lastly argue that there is an economic benefit of not having to put every gene on a microarray for cell differentiation study. In response the claimed polynucleotides are a tiny set of such polynucleotides and does not claim a negative set that is not to be placed on such a microarray. Therefore, it is not seen what is "cut down" or "simplified".

In summary, for the reasons of record and as further explained above the instant invention still is deemed properly to be rejected for a lack of utility.

LACK OF ENABLEMENT

Claims 3 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, since the claimed invention is not supported by a combination of specific, substantial, and credible utility, or, in the alternative, a well-established utility for the reasons maintained as set forth above, one skilled in the art would not know how to use the claimed invention. This rejection has not been separately argued by applicants from the above lack of utility rejection and is also therefore maintained from the previous office action, mailed 6/3/03.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

March 18, 2004


ARDIN H. MARSCHEL
PRIMARY EXAMINER 3/18/04